REMARKS/ARGUMENTS

Applicants respectfully request reconsideration of the above-identified application. Claims 1-29 currently are pending, with claims 13-29 having been withdrawn as being directed to the non-elected species.

With the present response, page 19, line 35 of the specification has been amended to correct a typographical error. Width W_B has been changed from "0.008 inch" to --0.08 inch--. As amended, the specification now is consistent with claim 6 as originally filed. Claim 11 also has been amended to correct a typographical error. The term "polymetric" has been changed to --polymeric--. See, for example, Application at page 7, lines 3-5; page 18, lines 15-16; and page 19, lines 28-30. No new matter is added by virtue of these amendments.

I. Claim Objections

Claims 6, 7, and 9 have been objected to as reciting the term "about." This term has been objected to as being a relative term and, therefore, believed to render the claims indefinite.

Claims 6 recites that "said leaf drive component first width is about 0.080 inch" and said leaf drive component second full width is about 0.060 inch". Claim 7 recites "said leaf cable guide coupling portion oppositely disposed rearward end surface has a widthwise extent of about 0.010 inch." Claim 9 recites "an internal diametric extent of about 0.015 inch."

The term "about" is conventionally used in patent claims to mean near to in quality, degree, etc. In the present application, the skilled artisan can readily ascertain the acceptable degree of variation by referring to the specification which defines the relationships among the disputed components and provides for reasonable tolerance in the recited widths. For example, as noted at page 19, lines 24-26, the capture component 340 is contained within the internal structure of support component 32. As such, the dimensions of the capture component's constituent components must be selected to be commensurate with the dimensions of support component 32. Looking to page 19, line 24 -page 20, line 19, the individual elements of capture component 340 are set forth. Capture component 340 comprises a plurality of leafs, each having a drive component and a polymeric guide component. With respect to the drive component, each leaf has a base region with a width W_B. Each leaf also has a guide support region with a full width, W_F, and a serrated edge of minimum width, W_N, less than the full-width W_F. As the specification goes on to say: from a structural standpoint, the effective widths of the region 370 will lie somewhere between the value W_N and W_F; with the dimensions, W_B and W_F, each shoulder will have a lengthwise extent of about 0.010 inch; the interior diameter of the guide channel is selected to receive two of the nineteen stainless steel cables which have a

nominal diameter of about 0.006 inch. In view of the guidance provided in the specification, the claims at issue are not ambiguous as the degree of variation permitted is readily ascertainable by the skilled artisan.

II. Double Patenting

A. Claim 1 stands rejected on the ground of non-statutory obviousness-type double patenting in view of claims 18, 26, 30 and 35 of U.S. Patent No. 6,287,304.

Applicants respectfully submit that the non-statutory obviousness-type double patenting rejection is improper as claim 1 of the present invention is not obvious in view of claims 18, 26, 30 and 35 of U.S. Patent No. 6,287,304.

Commonly owned U.S. Patent No. 6,287,304 discloses apparatus and method for the interstitial cauterization of tissue. A tissue specimen is not removed for analysis. Rather, the forward end of the instrument is positioned adjacent a suspect lesion having a given tissue volume. A pair of electrode assemblies are deployed outwardly from the instrument on opposite sides of the target tissue volume. Once deployed, the electrode assemblies carry out a bioactive cauterization procedure using relatively lower current densities to elevate the temperature of the targeted tissue volume to a level evoking irreversible cell death. Such a procedure avoids "seeding" where malignancy is present.

Beginning with U.S. Patent No. 6,277,083, the inventors of the commonly owned patents at issue began developing a different biopsy technology from that of the '304 patent. The '083 patent discloses a tissue capture device and method for removing a tissue volume that upon removal from the body may be sent to pathology for analysis. One embodiment disclosed in the '803 patent includes a tubular delivery cannula of minimum outer diameter, the tip or distal end of which is positioned in confronting adjacency with the tumor or tissue volume to be removed. Positioned within an interior channel of this delivery cannula is a generally tubular-shaped capture component which is configured having an expansible forward portion extending to a forwardly disposed leading edge portion. That leading edge portion carries out electrosurgical cutting. A deployment assembly, configured with the delivery channel and the capture component, functions to move the capture component forward portion toward the region of the tumor. This movement also causes that forward portion to expand as its leading edge portion electrosurgically cuts through healthy tissue adjacent the targeted tumor. Upon completion of the expansion, the forward region of the capture component will generally extend about the targeted tumor and a component of adjacent healthy tissue, whereupon the deployment assembly causes the electrosurgically cutting leading edge portion to be contracted while

continuing to cut, toward a closed orientation. This effects a circumscribing isolation of the targeted and adjacent tissue. The delivery cannula then is removed with the tissue specimen containing capture component. The different approaches of the '304 and '083 patents may be seen by comparing Fig. 15-21 of the '304 patent with Figs. 39-41 of the '083 patent.

The '659 patent, which is a continuation-in-part of the '083 patent, additionally discloses a forwardly disposed precursor assembly that facilitates positioning of the instrument adjacent the tissue volume to be removed. The capture component also was improved by the use of a plurality of leafs, each terminating in an eyelet configuration. Extending through each eyelet is an electrically conductive pursing cable of a pursing cable assembly which is then attached to another leaf tip and extends rearwardly through a small, flexible guide tube attached to the leaf for connection with the cable terminator component of a drive assembly. The drive assembly is driven forwardly by a motor, translation assembly and abuttably engaged transfer assembly to actuate the capture component. This actuation is carried out by electrosurgically exciting the pursing cable assembly to establish a cutting leading edge. Then, the leafs, carrying the excited cable assembly, are driven at an attack angle mutually outwardly through a guidance assembly to an extent that the cutting leading edge reaches an effective maximum diameter extending about the tissue volume. At this juncture, the cable terminator encounters a stop member and the leaf tips are drawn mutually inwardly to define a curvilinear profile to close the leading edge about the tissue volume as their forward movement continues. These pursing cables, now under stress and constrained within the guide tubes at the outer surfaces of the leafs, contribute to the structural stability of the resultant tissue specimen containment structure.

The present invention improves upon the above-described capture component in that the forwardly disposed stainless steel guide support region of each leaf is formed with a diminished widthwise extent and is enclosed within an extruded polymeric cable guide. This not only provides an improved leaf cable guide function but permits enhanced flexure at the tip region of each leaf. That enhanced flexure promotes a steeper angle of attack during the pursing activity to, in turn, improve the cutting profile of the advancing and pursing cutting cable leading edge.

Looking to claim 1 of the present application, it may be seen that that claim recites the above-described features which are readily distinguishable from the technology claimed in the '304 patent.

Most notably, claim 1 of the present invention recites:

> a tissue capture component positioned within said interior channel, having a leaf assembly comprising a plurality of elongate thin leafs extending forwardly from a base portion to a leaf tip region, a said

> leaf having a resilient drive component extending along a leaf axis from said base portion to a tip region, and an electrically insulative flexible leaf cable guide component having one or more guide channels deposed parallel with said leaf axis and extending to a guide outlet, and an integrally formed coupling portion mounted with said drive component, a said guide channel extending from said tip region along said drive component to a guide commencement location, said leaf assembly being moveable to deploy outwardly from said support member forward region, said capture component having a pursing cable assembly extending through a said cable guide component guide channel and said guide outlet, electrosurgically energizable and deployable with each said leaf tip region to define an electrosurgical cutting arc of initially expanding extent and subsequent pursively contracting extent;
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> Claim 1, lines 4-16.

Claim 1 also recites drive and control assemblies to effect the recited pursing cable assembly's electrosurgical cutting arc of initially expanding extent and subsequent pursively contracting extent. Claim 1, lines 17-23.

Such a tissue capture component, specifically including a pursing cable assembly, and associated drive and control assemblies are neither disclosed nor reasonably suggested by claims 18, 26, 30, or 35 of the '304 patent. Independent claim 18 recites a support member having an electrode deployment portion. Within the deployment portion is a first electrode assembly deployable to move outwardly to a cauterization orientation. To effect that deployment, claim 18 recites an electrosurgical generator that generates a cutting current and a cauterization current. A support member includes a deployment portion within which extends an electrode assembly. An actuator assembly is mechanically connected with the first electrode assembly to deploy the electrode assembly outwardly to a cauterization orientation. A control assembly is provided to control the electrosurgical generator.

Claim 26, dependent from claim 18, further recites that the deployment portion is outwardly open extending along the forward end region of the support member; the first electrode assembly first primary component is thin, elongate, and resilient extending an arch defining distance beyond the rearward location; and the actuator assembly is configured to deploy the first electrode first primary component by urging it forwardly in compression to an extent curving it into an outwardly depending arch formation. See, for example, Figs. 1-3 and Col. 8, line 53 to Col. 10, line 48, which illustrate a support member 42 having a pair of deployment portions which are open slots 80 and 82. Extending within the deployment slots are a pair of electrodes 52 and 54. Fig. 2 shows that the distal ends of electrodes 52 and 54 extend forwardly of slots 80 and 82 to an abutting form of connection with a support structure just rear

of the instrument tip 44. Fig. 3 reveals the arch structure developed when component 54 is urged forwardly in compression upon actuation of the actuator assembly, 56. Comparing this claimed embodiment to that of the present apparatus, it may be seen that claims 18 and 26 provide for a completely different structure that that disclosed and claimed in the present application.

Claim 30, dependent on claim 26, further recites that the first electrode assembly comprises a thin membranous flexible polymeric first secondary electrode support, suspended from said first primary component substantially between said forward location and said rearward location and having slot defined panels; a first secondary electrode provided as an electrically conductive surface supported upon said first secondary electrode support panels; and said first secondary electrode being foldably nested with said first secondary electrode support within said electrode deployment portion during said insertion mode, and depending from said first primary component toward said deployment portion when said first primary component is in said first cauterization orientation.

Depending from claim 26, claim 30 again employs an electrode deployable to an arch-shaped configuration. Figs. 30-34 illustrate an embodiment of the invention recited in claim 30 having the membranous electrode. See Col. 28, lines 3 to Col. 29, line 22. A primary electrode component is identified at 664. Supported from and deployed downwardly or unfurled from the primary electrode is sheet-form membranous second electrode 666 formed as a flexible circuit fashioned of a series of flexible panels 668a-668d. The folding or nesting of these components during insertion mode is shown in Fig. 33 and described at Col. 29, lines 8-22. Again, this configuration clearly is a different approach than that of the present application which employs a tissue capture component with a pursing cable assembly for encapsulating a tissue specimen.

Claim 35, also dependent on claim 26, additionally recites "an array of thin, flexible electrically conductive first secondary electrodes each having an outer end connected in electrically isolative association with the first electrode first primary component and having an inner end connected within said deployment portion, said first secondary electrodes extending from said first electrode first primary component into said deployment portion when said first electrode first primary component is in said first cauterization orientation, and being retained within said support member electrode deployment portion during said insertion mode."

Fig. 26 illustrates an embodiment of the invention recited in claim 35. See Col. 25, line 33 to Col. 26, line 12. In Fig. 26, an array of electrodes 556. These electrodes are seen to extend from the slot-shaped deployment portion 544. An array of electrically insulative sleeves 558 is provided to accommodate for the presence of electrically conductive region 542.

None of the claims at issue in the '304 patent disclose or suggest a apparatus with a tissue capture component, drive assembly and control assembly as recited in claim 1 of the present application. Claims 18, 26, 30 and 35 of the '304 patent teach a completely different methodology. Claim 1 of the present application does not simply recite the same elements as the '304 patent claims except with different names. Claim 1 recites different terminology because it defines a different structure.

In view of the above, Applicants respectfully request that the double patenting rejection of claim 1 in view of claims 18, 26, 30 and 35 of the '304 patent be withdrawn.

B. Non-statutory obviousness-type double patenting rejection in view of U.S. Patent Nos. 6,471,659 and 6,923,809

Upon an indication of allowable subject matter, Applicants will submit terminal disclaimers to obviate the double patenting rejections in view of U.S. Patent Nos. 6,471,659 and 6,923,809. Such terminal disclaimers are proffered in order to materially advance prosecution but without admitting the propriety of the rejections.

C. Non-statutory obviousness-type double patenting provisional rejection in view of copending Application No. 10/630,336

Upon an indication of allowable subject matter, Applicants will submit a terminal disclaimer to obviate the provisional double patenting rejection in view of copending Application No. 10/630,336. Such a terminal disclaimer is proffered in order to materially advance prosecution but without admitting the propriety of the rejection.

III. Novelty

Claims 1-5, 8, 11, and 12 stand rejected under 35 U.S.C. § 102 (b) as being anticipated by U.S. Published Application No. 2002/0072688 issued to Burbank, et al. (hereinafter, "Burbank").

Applicants respectfully submit that Burbank discloses almost none of the recited elements of claim 1. Specifically, claim 1 requires a leaf assembly comprising a plurality of leafs each leaf having a drive component, a cable guide component with one or more guide channels and a guide outlet, and an integrally formed coupling portion. Claim 1 also requires that the leaf assembly deploy outwardly from the support member forward region. Additionally, claim 1 recites a pursing cable assembly extending through a guide channel of a cable guide component that is electrosurgically energizable and deployable with each leaf tip region to

define a cutting arc of initially expanding extent and subsequent pursively contracting extent. All of these elements are lacking in Burbank.

In order to circumscribe a volume of tissue, Burbank employs an arch-shaped electrode (20), or plurality of electrodes (20b), that is deployed from a slot extending along a support member. Electrode 20's distal end is anchored to a shaft 18 so that movement of the electrode 20's proximal end causes the electrode to radially expand outwardly from slot 48 to the bowed configuration shown, for example, in Fig. 1. Once deployed, the instrument is rotated to separate the selected sample from surrounding tissue. See paragraphs 0041, 0043, 0044.

The present device, however, does not use such an electrode. Rather, as recited in claim 1 the present device employs an electrosurgically energizable pursing cable assembly that is deployed with a leaf assembly that extends outwardly from the forward region of the support member. The pursing cable assembly defines an electrosurgical cutting arc of initially expanding extent and subsequent pursively contracting extent in order to circumscribe a tissue sample. Such a pursing cable assembly and its expanding and pursively contracting deployment are illustrated, for example, in Figs. 20 and 21. In those figures, a plurality of cables, 420-424, are seen connected to the tip regions of a leaf assembly including five leafs, 300-304. Fig. 20 shows the leaf assembly in an initial position, while Fig. 21 shows the leaf assembly having been extended to about one half of the available total axial distance from the instrument forward region 34. Fig. 5 shows the instrument in a fully deployed configuration with the pursing cable assembly having been contracted to form a capture basket configuration, or tissue recovery cage, substantially encapsulating the entire target tissue volume.

Burbank does not disclose a "pursing cable assembly." Burbank's element 16, cited as being a pursing cable assembly, is simply a wire extending along a conventional trocar tip. Element 16 is energized to advance the trocar tip to a position adjacent or within a given tissue volume. Element 16 is not employed in Burbank's tissue isolation. That function is performed solely by electrode 20 or electrodes 20b. See Paragraphs 0032 and 0038. The cutting element of Burbank also does not deploy outwardly from the support portion forward region as required by claim 1. Burbank's cutting electrode 20, 20b deploys radially outwardly from slot 48 which extends along support member 18. Also, Burbank's cutting element does not define an electrosurgical cutting arc of initially expanding then pursively contracting extent. Once electrode 20, 20b is fully deployed, it is rotated 360° in order to cut about the selected tissue volume. See paragraphs 0041, 0043, 0044. Alternatively, the electrode 20, 20b may be axially moved while rotating the instrument in order to dissect a cylindrical tissue volume. See Figs. 18 and 18 and accompanying specification text.

One of the primary features of the present application is that each leaf of the leaf assembly includes an "electrically insulative flexible leaf cable guide component". One embodiment of a cable guide component is illustrated in Fig. 12 of the application. As that figure shows, a cable guide component 400 includes a "guide channel" 408 and a "coupling portion" 406. A cable guide component surmounts each leaf as shown in Fig. 9, with cables of the pursing cable assembly extending through the appropriate guide channels. See claim 1, lines 12-14.

Element 23 of Burbank has been cited as the flexible leaf cable guide component. As noted in Paragraph 0033 of Burbank, "a layer of insulation 23 is disposed between the return electrode (comprising a major portion of the surface area of the shaft 18) and the portion of the shaft adjacent to the active electrode, which receives the cutting element 20 in its retracted position." See Fig. 3. Thus, element 23 is simply an insulative material coating the inside of the slot from which electrode 20 is deployed. Claim 1 recites "an integrally formed coupling portion mounted with said drive component". It should be noted that each leaf of the leaf assembly includes a drive component, such as those shown at 350-354 of Fig. 10. These should not be confused with the "drive assembly" recited in claim 1 that is actuatable to move the leaf assembly to deploy outwardly from the support member. The "coupling portion" cited as Burbank's element 35 is in fact a "gearing system" contained within the driver portion 24 of Burbank's instrument that rotates shaft 18. See paragraph 0036. As noted above, Burbank does not disclose a pursing cable assembly which is required by claim 1 to extend through the guide channel. Because Burbank does not include a pursing cable assembly, it also should be noted that Burbank lacks the "drive assembly" and "control assembly" recited for effecting deployment and electrosurgical energization of the pursing cable assembly.

Claims 2-5, 8, 11 and 12 depend from claim 1 and, therefore, should be considered patentable for the same reasons. These claims also recite additional features which further distinguish the claims from Burbank.

IV. Obviousness

Claims 6, 7, 9, and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Burbank, et al. The Examiner states that Burbank discloses the claimed invention but does not disclose expressly the dimensions and materials of the leaf cable drive and guide components. It is argued that these would have been an obvious matter of design choice to a person of ordinary skill in the art.

Applicants first note that Burbank does not disclose the claimed invention. See section III above regarding claim 1. Additionally, Burbank does not disclose the specific elements recited in claims 6, 7, 9, and 10, namely, leaf drive components having varying widths or a cable guide component having a cable guide coupling portion and channel guide.

Claim 6 recites that said leaf drive component first width is about 0.080 inch and said second full width is about 0.060 inch. Claim 1, from which claim 6 depends, recites "a leaf assembly comprising a plurality of elongate thin leafs... a said leaf having a resilient drive component". As noted above, a plurality of leafs are disclosed in Fig. 10, which also shows the leaf drive components 350-354. As further recited, a "drive assembly" is provided "to move said leaf assembly to move outwardly from said support member while effecting said deployment of said pursing cable assembly". Figs. 3-5. Burbank does not disclose a pursing cable assembly. Burbank also does not disclose a leaf assembly for expanding and contracting a pursing cable assembly. Since the claims require a plurality of leafs, each with a leaf drive component, there are of necessity a plurality of leaf drive components. Burbank also does not disclose a plurality of leaf drive components. Burbank does not disclose a plurality of such components having variable width. Shaft 18, a single component of unvarying width, is cited as being a leaf drive component. Clearly, this element cannot be the plurality of leaf drive components recited in the claims.

Also, contrary to the assertion that the specification does not teach that the recited dimensions provide an advantage, it is noted that the specific dimensions taught "an enhanced flexure at the tip region is provided. That enhanced flexure promotes a steep angle of attack during the capture component pursing activity." Application, page 21, line 36 to page 22, line 3. As such, these dimensions are not simply a matter of design choice.

With respect to claim 7, Applicants note again that Burbank does not disclose a coupling portion as recited in the claims. The element identified as a coupling portion in Burbank is gearing system 35 contained within the driver portion 24 of Burbank's instrument that rotates shaft 18. The dimensions of the coupling portion correspond with those of the leaf drive component first width and leaf drive component second full width. See Application, page 20, lines 17-18. As such, the selected widthwise extent contributes to the noted enhanced flexure at the tip region.

Claim 9 further recites that "said guide channel exhibits an internal diametric extent of about 0.015 inch." As noted above with respect to claim 1, Burbank does not disclose a guide channel as recited by the claims. Applicants further note that the diametric extent of the guide

channel is selected to accommodate the cables of the pursing cable assembly extending therethrough. See Application, page 20, lines 32-34.

Finally, claim 10 recites that "said leaf cable guide component polymeric material is polytetrafluoroethylene." Burbank does not disclose a cable guide component. Additionally, as noted at page, 21, lines 30-33 of the application, this material was specifically selected so that "the surfaces of the leaf structures will exhibit less friction with respect to the instrument guidance features as they emerge from the forward region 34 of the instrument 12."

In view of the above, claims 6, 7 9, and 10 are not obvious in view of Burbank.

V. Conclusion

In view of the above, wherein the claim program is seen to be patentable over the cited prior art, Applicants respectfully solicit issuance of a Notice of Allowance.

Respectfully submitted,

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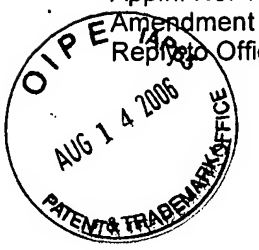

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